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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,796	03/13/2000	DOMINIQUE BRASSART	P99.2625	1391

29157 7590 11/19/2002

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EXAMINER
AFREMOVA, VERA

ART UNIT	PAPER NUMBER
1651	21

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/445,796	Applicant(s) Brassart et al.
	Examiner Vera Afremova	Art Unit 1651

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 3, 2002*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *11-14, 16-19, and 21-26* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *11-14, 16-19, and 21-26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 11-14, 16-19 and 21-26 as amended [Paper No. 20 filed 9/03/2002] are pending and under examination in the instant office action.

Claims 1-10 were canceled by applicants in the Paper No. 10 filed 6/04/2001.

Claims 15 and 20 were canceled by applicants in the Paper No. 20 filed 9/03/2002.

Deposit

The deposit requirement for *Lactobacillus johnsonii* CNCM I-1225 has been met in the Paper No. 10 filed 6/04/2001.

Claim Rejections - 35 U.S.C. § 112

Claims 11-14, 16-18 and 26 remain rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as explained in the prior office action and for the reasons below as explained in the prior office action.

Claim 11 remains indefinite as explained in the prior office action with regard to the differences between "treatment" and "prophylaxis", if any, in the method of administration of identical compositions for both "treatment" and "prophylaxis as claimed.

Claim 26 remains indefinite as explained in the prior office action because of a recitation of "cfu/ml" wherein amounts of the composition are expressed by volume however the nature of the claimed nutritional composition is not specified (see claim 23).

Claim Rejections - 35 U.S.C. § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-13, 16-19, 21-25 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by US 5,578,302 [B] as explained in the prior office action and for the reasons below.

Claims 11-14, 16-19 and 21-26 as amended remain rejected under 35 U.S.C. 102(b) as being anticipated by US 5,494,664 [A] as explained in the prior office action and for the reasons below.

The claims are directed to methods for treatment or prophylaxis of mineral deficiencies in a mammal or for improving absorption of minerals from the diet wherein the methods comprise step of enterally administering to a mammal at risk of calcium deficiency a nutritional composition comprising one or more *Lactobacillus* bacteria. Some claims are further drawn to the use of *Lactobacillus sp.* CNCM I-1225 in the method of administration of the nutritional composition. Some claims are further drawn to the use of milk products and/or milk hydrolysates in the nutritional composition in the method of administration. Some claims (14 and 26) are further drawn to the use of lactobacteria in amounts 10^{7} to 10^{11} CFU/ml in the method of administration of the nutritional composition.

The cited US 5,578,302 [B] and US 5,494,664 [A] are relied upon as explained in the prior office action and repeated herein.

US 5,578,302 [B] (abstract) teaches a method for improving mammal health wherein the method comprises enterally administering to a mammal a nutritional composition which contains bacteria belonging to the genus *Lactobacillus* including particular strain *Lactobacillus johnsonii (acidophilus)* CNCM I-1225 (col. 2, line 13) in nutritional composition in a form of yogurt or milk-based powdered formulations (col.1, lines 43-44).

US 5,494,664 [A] (col. 1, line 43-60 and col. 2, line 14) teaches a method for improving mammal health wherein the method comprises enterally administering to a mammal a nutritional composition which contains lactobacteria and/or bifidobacteria including *Lactobacillus acidophilus (johnsonii)* CNCM I-1225 in amounts 10^7 to 10^8 CFU/ml in nutritional composition in a form of yogurt or other milk-based product.

The cited patents are considered to anticipate the claimed invention because the methods of the cited patents are one active step methods which comprise one step of enterally administering an identical composition comprising one or more bacteria belonging to the genus of *Lactobacillus* or one or more bacteria belonging to the strain CNCM I-1225 belonging to the species of *Lactobacillus johnsonii (*priory identified as *acidophilus)* to identical an identical mammalian patient as the claimed method. Consequently, the results of practicing identical protocols of administering are reasonably expected to be identical as intended and as claimed. Both methods of the cited patents comprise the use of compositions with milk ingredients as well as ingredients of whole cell preparations derived from one or more *Lactobacillus* bacteria as the claimed method, and, thus, administration of identical compositions with identical components

as claimed are reasonably expected to inherently provide mammalian patients with benefits related to treatment or prophylaxis of mineral deficiencies including calcium deficiency or for improving absorption of minerals including calcium from the diet as intended for the claimed method. Moreover, the method of US 5,494,664 [A] teaches the use of nutritional compositions with that same amounts of the same bacterial strain CNCM I-1225 as the claimed method. Thus, identical benefits are inherent to the administration. Therefore, the methods are identical as disclosed and as claimed.

Claim Rejections - 35 U.S.C. § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-14, 16-19 and 21-26 as amended remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,578,302 [B] or US 5,494,664 [A] taken with Yaeshima [IDS-3-AR], Yoshida [U] and Sellars [U-19] as explained in the prior office action and for the reasons below.

The claims are directed to methods for treatment or prophylaxis of mineral deficiencies in a mammal or for improving absorption of minerals from the diet wherein the methods comprise step of enterally administering to a mammal at risk of calcium deficiency a nutritional composition comprising one or more bacteria belonging to the genus of *Lactobacillus* bacteria. Some claims are further drawn to the use of particular strain CNCM I-1225 belonging to

*Lactobacillus johnsonii (*priory identified as *acidophilus)* in the method of administration of the nutritional composition. Some claims are further drawn to the use of milk products and/or milk hydrolysates in the nutritional composition in the method of administration. Some claims are further drawn to the use of bacteria in amounts 10^7 to 10^{11} CFU/ml in the method of administration of the nutritional composition.

The cited patents US 5,578,302 [B] or US 5,494,664 [A] are relied upon as explained above for the disclosure of the methods of administering nutritional compositions comprising bacteria belonging to the genus of *Lactobacillus* including particular strain CNCM I-1225 *Lactobacillus johnsonii (*priory identified as *acidophilus)*. The cited methods clearly teach health improvement in the health of mammals as the result of administering compositions with various lactobacteria including bacteria that which are presently claimed. However the cited patents are silent with regard to particular effects as claimed such as treatment or prophylaxis of mineral deficiencies including calcium in a mammal or for improving absorption of minerals including calcium from the diet.

However, the references by Yaeshima [IDS-3-AR] and Yoshida [U] teaches method for treatment and/or improving mineral absorption by administering lactobacteria or bifidobacteria to mammals. For example: the cited references by Yaeshima [IDS-3-AR] (page 41) and Yoshida [U] (abstract) disclose a method for increasing absorption of minerals including calcium from the diet wherein the method comprises enterally administering to a mammal a nutritional composition with lactobacteria or bifidobacteria including representatives of the genus

Bifidobacterium alone or with additional products such as dietary fibers (oligosaccharides or lactulose) and minerals (calcium, magnesium, etc.).

Further, the reference by Sellars [U-19] teaches that the acidophilus products comprising representatives of bacterial genera *Lactobacillus* and/or *Bifidobacterium* or including representatives of bacterial species *Lactobacillus acidophilus* (see tables I-III at pages 84-86) are known to exhibit health promoting properties associated with establishment of an acidophilus microflora in mammals including the health benefit such as increasing rate of mineral absorption or increasing bioavailability of minerals (page 100, par. 3). The references also teaches that the consumption of fermented diary products containing lactobacteria increases mineral absorption from diets depending on age and state of various patients (page 102, par. 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use bacteria belonging to the genus *Lactobacillus* or to the strain CNCM I-1225, which is *Lactobacillus johnsonii (*priory identified as *acidophilus),* in the method of administering to mammals with a reasonable expectation of success in treating mineral deficiencies including calcium deficiency in mammals and/or improving absorption of minerals including calcium from diets because consumption of products comprising various lactobacteria including bacteria belonging to *Lactobacillus* and/or *Bifidobacterium* or including bacteria belonging to the species of *Lactobacillus acidophilus* been taught and suggested in the prior art for promoting mammalian health including health benefits such as increasing mineral absorption including calcium absorption from diets. Further, it is considered to be within the

skills of an ordinary practitioner in the field to adjust amounts and components of the nutritional compositions intended for treatment or prophylaxis of mineral deficiencies or for improving absorption of minerals from diets depending on patient age, life style and/or general state of health. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicants' arguments filed 9/02/2002 have been fully considered but they are not persuasive.

With regard to the claim rejections under 35 U.S.C. 102(b) as being anticipated by US 5,578,302 [B] or US 5,494,664 [A] applicants argue that the cited patents do not suggest capability of lactobacteria for improving absorption of minerals from the diet (see response page 3, par. 1-2). This is not found persuasive because the cited methods and the presently claimed method are one active step methods comprising one step of enterally administering to a mammal an identical composition with identical lactobacteria belonging to identical strain *Lactobacillus sp.* CNCM I-1225 {US'664 or US'302} at identical amount such as 10x7 to 10x8 CFU/ml {US'664}. Thus, the final result as disclosed and as claimed is inherently identical as the result of administration of identical composition with identical lactobacteria. In order to qualify as an anticipatory reference, the disclosure need not be express. Even failure of those skilled in the art

to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation: In *Atlas Powder Co. v. IRECO, Inc.*, 51 USPQ2d 1943 (Fed. Cir. 1999). Thus applicants are incorrect in arguing that the anticipatory rejection is improper and must be certain.

With regard to the claim rejection under 35 U.S.C. § 103 applicants argue that the secondary references do not suggest capability of lactobacteria for improving absorption of minerals from the diets (response pages 3-4).

In particular, with regard to Sellars [U-19] applicant argue that it teaches the benefits of fermented product with lactobacteria rather than lactic bacteria in the milk products as a causative agents of improving absorption of minerals from the diet (page 4, last par.) However, the claimed invention is drawn to administration of a generic lactobacteria containing nutritional product (claims 11, 19 and 23). Moreover, the claimed invention does not exclude the lactobacteria fermented products because some of the claims are drawn to the use of products with milk components (claim 16).

With regard to the cited reference by Yaeshima [IDS-3] applicants appear to argue that lactobacteria alone does not provides the same improvement in calcium absorption as combination of lactobacteria with lactulose. Yet, the claimed invention does not exclude incorporation of lactulose. Besides, the cited reference by Yaeshima [IDS-3] teaches that absorption of calcium has been improved as the result of administration of both compositions

comprising lactobacteria with and/or without lactulose over control diet without lactobacteria (figure 13).

With regard to the disclosure by the Yosida's reference [U] applicants appear to argue that it teaches away since no differences in "deleterious" or harmful effects are found between the germ free and the lactobacteria inoculated animals with regard to mineral absorption. Unlike the applicants' opinion the Yosida's reference remarks and/or conclusions do not provide a reasonable basis to teach away from the beneficial use of lactobacteria as a well known health promoting agent. Although the disclosure by the Yosida's reference is limited with regard to additional components in mammalian diets and their effects in the method of administration of lactic acid producing bacteria for absorption of minerals, nevertheless, it teaches the same, if not identical, method of administering lactic acid producing bacteria to mammal with the same, if not identical, effects at least as related to "prophylaxis" of mineral absorption or deficiencies including calcium absorption or deficiencies for the mammals at risk of calcium deficiency as it is encompassed by the present invention and/or claims.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

Art Unit 1651

November 8, 2002.

IRENE MARX
PRIMARY EXAMINER